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UNITED STATE DEPARTMENT OF COMMERCE Patent and Trademark Office

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APPLICATION NO. **FILING DATE** FIRST NAMED INVENTOR ATTORNEY DOCK T NO. 09/557,473 04/24/00 HAMLIN R 10527-003007 **EXAMINER** IM22/0830 JOHN J GAGEL DYE, R FISH & RICHARDSON P C ART UNIT PAPER NUMBER 225 FRANKLIN STREET BOSTON MA 02110-2804 1772 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

08/30/00

Application No.

Applicances)

Hamlin

Office Action Summary Examiner

Rena L. Dye

09/557,473

Group Art Unit 1772

Responsive to communication(s) filed on Apr 24, 2000	·
☐ This action is FINAL .	
☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.	
A shortened statutory period for response to this action is set to is longer, from the mailing date of this communication. Failure to application to become abandoned. (35 U.S.C. § 133). Extensio 37 CFR 1.136(a).	o respond within the period for response will cause the
Disposition of Claims	
	is/are pending in the application.
Of the above, claim(s)	is/are withdrawn from consideration.
Claim(s)	is/are allowed.
	is/are rejected.
Claim(s)	is/are objected to.
☐ Claims	are subject to restriction or election requirement.
Application Papers	
☐ See the attached Notice of Draftsperson's Patent Drawing	
☐ The drawing(s) filed on is/are objected	
☐ The proposed drawing correction, filed on	is 🗀 approved 🗀 disapproved.
☐ The specification is objected to by the Examiner.	
☐ The oath or declaration is objected to by the Examiner.	
Priority under 35 U.S.C. § 119	
Acknowledgement is made of a claim for foreign priority to	
☐ All ☐ Some* ☐ None of the CERTIFIED copies of	the priority documents have been
☐ received.☐ received in Application No. (Series Code/Serial Num	shor)
received in this national stage application from the	
Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).	
Attachment(s)	
☐ Information Disclosure Statement(s), PTO-1449, Paper No.	o(s)
☐ Interview Summary, PTO-413	Q
 Notice of Draftsperson's Patent Drawing Review, PTO-94 Notice of Informal Patent Application, PTO-152 	O
Notice of informal Patent Application, P10-192	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

Art Unit: 1772

DETAILED ACTION

Page 2

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 26-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdrahala (5,248,305).

Zdrahala teaches an extruded catheter and other flexible plastic tubing manufactured from a liquid crystal polymer (LCP) (Figure 3; column 2, lines 13-28). The extruded LCP material may be coated, by coextrusion or subsequent extrusion, with a layer of typically non-liquid crystal polymer formulation which has tissue compatible characteristics. Also or alternatively, the coating may be on the inner surface of the tube of liquid crystal polymer material (column 2, lines 28-39). The coating may be a smooth, hemocompatible surface plastic material which may have lubricating characteristics. Coating materials are listed at column 4, lines 34-50 and are different materials than that of the LCP. Tubes extruded in accordance with this invention for catheters or any other use may be biaxially oriented in that they may be longitudinally stretched, simultaneously with the rotation of the extrusion die (column 4, lines 55-61).

Art Unit: 1772

Although Zdrahala fails to expressly teach a balloon, it is the Examiner's position that a balloon configured to be attached to a catheter would be included in the teaching of "extruded catheters and *other flexible plastic tubing*". Therefore, it would have been obvious to one having ordinary skill in the art to have made a balloon catheter from the materials taught by Zdrahala.

Since Zdrahala teaches that which appears to be identical to the recited claims with respect to the material, the recited "wherein the balloon has a radial expansion not exceeding 3-10 percent when inflated to seven atmospheres" would be inherent.

Although Zdrahala does not expressly teach the second layer as an adhesion layer, Zdrahala does teach that the extruded catheter body may then have applied to it the customary parts, connections and the like used in the manufacture of conventional catheters of every type (column 4, lines 51-54). Therefore, it would have been obvious to one having ordinary skill in the art to have provided the inner layer with a polymer having adhesive properties so that the catheter could be connected to other parts.

Double Patenting

3. Claims 26-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,270,086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recited in the present patent application are broad enough to include or overlap with that which is recited in '086. The comprising language recited in independent claim 26 is broad

Art Unit: 1772

enough to include the recited outer tensile layer and inner bonding layer of '086. Furthermore, '086 defines the outer tensile layer as including LCP (column 2, lines 31-42).

4. Claims 26-38 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-50 of copending Application No. 087/907,170. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recited in the present patent application are broad enough to include or overlap with that which is recited in '170. The comprising language recited in independent claim 26 is broad enough to include the recited first layer of a biaxially oriented polymer (polyester) and a second layer or a biaxially oriented polymer (polyelefin).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Dye whose telephone number is (703) 308-4331.

Rena L. Dye Primary Examiner Tech Center 1700

R. Dye August 27, 2000